K113219

6. 510(K) SUMMARY

OCT 19 2012

Ellipse Intramedullary Limb Lengthening System
510(k) Summary – K TBD
October 2011

1. **Company:** Ellipse Technologies, Incorporated
13900 Alton Parkway, Suite 123
Irvine, CA 92618

Contact: John McIntyre
Vice President, RA/QA/CA

2. **Proprietary Trade Name:** Ellipse PRECICE Intramedullary Limb Lengthening System

3. **Classification Name:** Rod, Fixation, Intramedullary and Accessories

(21 CFR 888.3020)

4. **Product Code:** HSB

5. **Product Description:**

The Ellipse PRECICE Intramedullary Limb Lengthening System is composed of a modular implantable intramedullary rod ("Distracting Rod"), locking screws, an external remote controller (ERC), and surgical implantation tools and accessories. The modular implantable rod is available in different configurations, lengths, and diameters to accommodate a variety of patient anatomies. Likewise, the locking screws are available in two different diameters and a variety of lengths from 20 mm to 75 mm in 5 mm increments. The distracting rod is a modular system that includes the PRECICE Actuator component and various configurations of PRECICE Extension Rods. The PRECICE Actuator includes an enclosed rare earth magnet, telescoping lead screw/nut assembly and gearing. The PRECICE Actuator is supplied sterile by gamma sterilization while the

PRECICE IMLL Extension Rods, locking screws, and reusable accessories are supplied non-sterile and must be sterilized prior to use.

The External Remote Controller (ERC) is a non-invasive adjustment component of the system. The ERC is electrically powered and is used for non-invasive lengthening of the implanted rod. The ERC can be used by the physician or by the patient in the home environment to perform lengthening.

6. Indications

The Ellipse PRECICE Intramedullary Limb Lengthening System is indicated for limb lengthening of the tibia and femurs.

7. Substantial equivalence

Documentation demonstrates substantial equivalence to the Ellipse Intramedullary Limb Lengthening System cleared under K101997 (cleared on July 12, 2011). The purpose of this premarket notification is to include additional labeling materials for the Home Use of the ERC by the patient. Therefore, data provided in this submission only includes information relevant to the Home Use of the ERC by the patient. Substantial equivalence is based on similar indications for use, designs, *in vitro* testing, and Usability evaluations performed. The *in vitro* evaluations included specific tests performed on the ERC to demonstrate the suitability of the ERC for use in the home by the patient. In addition, Usability evaluation of the ERC in a representative population was performed to demonstrate its suitability for use in the proposed patient population and in accordance with the indications.

With the exception of the Home Use of the External Remote Controller by the patient, the implant and the accessories to the system are identical between the Ellipse PRECICE IMLL System and the predicate described in K101997.

No changes in the design of the implant are included in this premarket submission. Specifically, the Ellipse PRECICE IMLL System and the predicate devices are both

designed to be implanted into the medullary canal of the femur or tibia. These devices are available in a variety of geometrical configurations and diameters/lengths to accommodate a variety of patient anatomies. Both devices are designed as a telescoping rod that can be lengthened non-invasively with the use of the ERC.

The Ellipse PRECICE IMLL System was developed and evaluated in accordance with recognized standards and with in-house developed test methodologies. This testing includes risk assessment of the device specific to the home use, additional testing to applicable IEC standards for home use of medical electrical systems for use in the home healthcare environment, and a usability study undertaken on 30 subjects to evaluate the usability of the ERC in an equivalent patient population. Risk analysis for the home use of the device, labeling for the home use of the ERC, and test results are included in this premarket notification. The results of testing demonstrate that the Ellipse PRECICE IMLL System that is the subject of this premarket notification is substantially equivalent to the predicate device.

The following documentation and testing have been included in order to establish equivalence to the predicate device. Substantial equivalence is focused on the Home Use aspect of the ERC. Testing includes a usability evaluation for the Home Use of the ERC by the patient, minimum rated voltage testing, shock and vibration testing, and ingress protection testing performed in accordance with IEC 60601-1-11;2010. The following tests have been performed in order to establish equivalence to the predicate device:

Test/Document Description	Applicable test standard
Risk Management Report	EN ISO 14971:2007
Minimum rated voltage testing	IEC 60601-1-11:2010
Shock and Vibration Testing	IEC 60601-1-11:2010
Ingress protection	IEC 60601-1-11 :2010
Usability evaluation	n/a

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 19 2012

Ellipse Technologies, Inc.
% Mr. John McIntyre
Vice President, Regulatory, Quality, and Clinical Affairs
13900 Alton Parkway, Suite 123
Irvine, California 92618

Re: K113219
Trade/Device Name: Ellipse PRECICE Intramedullary Limb Lengthening System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: September 28, 2012
Received: October 1, 2012

Dear Mr. McIntyre:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: ~~Unknown~~ K113219

Device Name: Ellipse PRECICE Intramedullary Limb Lengthening System

Indications for Use: The Ellipse Intramedullary Limb Lengthening System is indicated for limb lengthening of the tibia and femurs.

Prescription Use ____x____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113219